UNITED STATES DEPARTMENT OF COMMERCE
**Patent and Trademark Office**
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

ID

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/280,270 | 03/29/99 | MACEVICZ S | 5525-0015.21 |

022918
IOTA PI LAW GROUP
350 CAMBRIDGE AVENUE SUITE 250
P O BOX 60850
PALO ALTO CA 94306-0850

HM12/0110

| EXAMINER | |
|---|---|
| LU,F | |
| **ART UNIT** | **PAPER NUMBER** |
| 1655 | 12 |

**DATE MAILED:** 01/10/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/280,270 | Applicant(s) Macevicz |
|---|---|---|
| | Examiner Frank Lu | Group Art Unit 1655 |

☒ Responsive to communication(s) filed on *Nov 20, 2000* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1, 20-25, 27-30, and 32* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 20-25, 27-30, and 32* is/are rejected.

☒ Claim(s) *22-25 and 30* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### *Drawings*

1. Formal drawings submitted on November 11, 2000 have been approved by the office.

### *Claim Rejections - 35 U.S.C. § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 20-25, 27-30, and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Note that claims 21-25, 27-30, and 32 are dependent on claim 20.

4. The term "subset" in claim 20 is a relative term which renders the claim indefinite. The term "subset" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

### *Claim Rejections - 35 USC § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 20, 21, 27-29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pease *et al.*, (Proc. Natl. Acad. Sci. USA, 91, 5022-5026, 1994) in view of the Stratagene Catalog (1994, page 109).

Pease *et al.*, teach light-generated oligonucleotide arrays for rapid DNA sequence analysis. In this study, 256 single-stranded, different octanucleotides which had different annealing temperatures were immobilized on a microchip. The hybridization pattern of fluorescently labeled oligonucleotide target was then detected by epifluorescence microscope (page 5022, abstract). An assay for oligonucleotide array was performed in a single hybridization temperature so that the most of oligonucleotides in an array could be efficiently used (page 5026, Figure 5).

Note that, in page 4, fourth paragraph of applicant's remarks, the applicant stated that "a stringency class is determined by '(a) ordering a set of oligonucleotides of all possible sequences of a given length according to the free energy of binding of each oligonucleotide to its complement, and (b) selecting a subset of consecutive oligonucleotides within this ordered set' " . Based on this definition, the examiner will considered that 256 single-stranded, different octanucleotides immobilized on a microchip (see the reference from Pease *et al.*) have or suggest "the same free energy of binding " and are from or suggest "the same stringency class" as described in claims 20, 21, 27-29, and 32.

Pease *et al.*, do not disclose a kit.

Stratagene catalog (1994, page 109) discloses DNA sequencing kits. The advantage of kit format is utilized not only assemble a variety of different reagents together but ensure the quality and compatibility of the reagents.

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have organized components in the method of Pease *et al.*, into a kit as suggested by Stratagene catalog (1994, page 109) because the method for rapid DNA sequencing analysis using light-generated oligonucleotide arrays was conventional at that time the inventions were made as cited in the reference. One having ordinary skill in the art would have been motivated to assemble reagents of the method described by Pease *et al.*, into a kit in order to obtain the above discussed advantage, thus resulting in instant kit described in claims 20, 21, 27-29, and 32. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to combine these prior art together because all of these prior art are known and are easy to use.

***Response to Arguments***

In page 5, fifth paragraph of applicant's remarks, applicant's argued that: (1) the prior art did not "suggest a subset of probe oligonucleotides, belonging to a single stringency class"; and (2) "Nor is there no any suggestion or motivation in the reference to provide subsets of oligonucleotides from a single stringency". These arguments have been fully considered but they are not persuasive to withdraw the rejection. The examiner noticed that, in page 4, fourth

paragraph of applicant's remarks, the applicant stated that "a stringency class is determined by '(a) ordering a set of oligonucleotides of all possible sequences of a given length according to the free energy of binding of each oligonucleotide to its complement, and (b) selecting a subset of consecutive oligonucleotides within this ordered set' ". However, it is still unclear what kind of oligonucleotide probes can be considered as "the same stringency class". For example, is any set of oligonucleotides of all possible sequences with the length of 8-12 base pair from "the same stringency class"? Since Pease *et al.*, taught a microchip immobilized 256 single-stranded, different octanucleotides wherein these oligonucleotides had different annealing temperatures and could be performed a hybridization assay in a single hybridization temperature, for the examination purpose, the examiner will considered that 256 single-stranded, different octanucleotides immobilized on a microchip (see the reference from Pease *et al.*) have or suggest "the same free energy of binding " and are from or suggest "the same stringency class". The rejection will remain.

***Double Patenting***

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

8. Claim 1 remains rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,750,341. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim 1 in this instant application and claim 1 of U.S. Patent No. 5,750,341 are directed to a method for identifying a sequence of nucleotides in a polynucleotide. Note that claim 1 in this instant application is much broader and has less method steps than claim 1 of U.S. Patent No. 5,750,341. Note that applicant did not address this issue.

***Conclusion***

9. Rejections found in the prior office action yet not restated herein above have been withdrawn.

10. Claim 22-25 and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if applicant can overcome 112 rejection and rewrite these claims in independent form including all of the limitations of the base claim.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claim is allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
January 7, 2001

Ethan Whisenant, Ph. D.
Primary Examiner (FSA)